

## **REMARKS**

The Office Action mailed on October 25, 2007 is acknowledged. Applicant requests examination of the above-mentioned application in view of the following remarks.

### **I. Claims; Abstract; Information Disclosure Statement**

By this Amendment, the claims have been amended and claims 2 and 4 have been cancelled without prejudice or disclaimer. Claims 4, 12, 13 and 15-31 have been withdrawn by the Examiner under a Restriction Requirement. Applicants respectfully are maintaining the withdrawn method claims for the purpose of rejoinder upon allowance of the non-restricted claims. Support for the claim amendments may be found throughout the specification.

For example, support for the amendments to Ar<sup>2</sup> in claim 1 is found on page 43 of the specification. Additionally, support for the amendments to X in claim 1 is found on page 45, line 30-33 of the specification.

Moreover, an abstract has been added on a separate sheet.

Furthermore, an Information Disclosure Statement disclosing US Patent Application Publication No. US 2007/0010560 is submitted herewith.

### **II. Rejections**

#### **Written Description Rejection**

Claims 1-3 and 6-11 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement.

The Examiner alleges that variables R<sup>6</sup>, Ar<sup>2</sup>, X, Y, and R<sup>7</sup>-R<sup>10</sup> are claimed broader than what is supported by the disclosure. Applicants, without acquiescing in the Examiner's rejection, have obviated the rejection by the amendments of Ar<sup>2</sup>, X and R<sup>8</sup>-R<sup>10</sup> to claim 1.

The Examiner further alleges that the only disclosure, in addition to the species reduced to practice, is in the form of lists of possible groups. The Examiner alleges that this is

a "laundry list" that does not constitute written description for the claimed genus. Applicants respectfully traverse this ground of rejection. The specification provides the skilled artisan with ample chemical structure information to immediately envision chemical species commensurate with the scope of the claimed genera of the rejected claims. See MPEP 2163 I.A.

The Examiner alleges that a correlation between structure and function for the claimed genus of compounds is neither known in the art nor disclosed in the specification and therefore which specific structural elements are essential for the activity of the claimed compounds as Raf kinase inhibitors is not known. Applicants respectfully traverse this ground of rejection. The rejected claims are directed to chemical compounds and not to specific structural elements essential for Raf Kinase inhibition activity. Applicants respectfully submit that the Examiner improperly is requiring the disclosure of the mechanism of action of the claimed compounds.

The Examiner states that a Structure/Activity Relationship (SAR) is not disclosed in the specification and therefore, it is not possible to determine what structural modifications will allow for the preservation of the desired activity. The Examiner maintains that common structural attributes of the claimed genus, combined with the structure and function, is neither disclosed in specification nor known in the art and therefore the specification is inadequate with respect to the written description requirement of 35 U.S.C. 112, first paragraph.

Applicants, would like to note that, according to MPEP Section §2163.04:

[t]he Examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims.

MPEP Section §2163.04 (I) further states that:

A general allegation of "unpredictability in the art" is not a sufficient reason to support a rejection for lack of adequate written description.

Furthermore, the Examiner asserts that disclosure of species supporting the claimed genera is limited to compounds actually reduced to practice. However, written description may be satisfied by the description of a representative number of species. Actual reduction to practice of species is not required. See MPEP Section §2163.05 (I) which states that:

[t]he written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species. A 'representative number of species' means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

It is clear therefore, that scope of the claimed genera is not limited to the compounds actually reduced to practice. In addition, the specification discloses numerous species falling within the genera of the rejected claims. In the view of the foregoing, applicants respectfully request reconsideration and withdrawal of the written description rejection.

#### Enablement

Claims 1-3 and 6-11 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. Applicants would like to submit that the Examiner is required to state what claim embodiments are enabled in the specification. The Examiner has stated that the specification is enabling for the use of compounds that have

adequate written description. Applicants, respectfully request that the Examiner clarify what he maintains are enabled claim embodiments.

The Examiner appears to allege that the rejected claims are not enabled because the specification does not contain SAR data directed to Raf Kinase inhibition.

Applicants respectfully traverse this rejection. As stated in MPEP Section §2164.02:

Compliance with the enablement requirement of 35 U.S.C. 112, first paragraph does not turn on whether an example is disclosed. An example may be "working" or "prophetic." An applicant need not have actually reduced the invention to practice prior to filing.

Accordingly, the law of enablement does not require reduction to practice or confirmatory data for a claimed invention. The enablement legal standard is whether the claimed invention may be made and used without undue experimentation. Applicants respectfully request reconsideration and withdrawal of the enablement rejection because determining the activity of the species falling within the claimed genera for Raf Kinase inhibition would not require undue experimentation as numerous routine methodologies are available to the skilled artisan to assess such activity of chemical compounds falling within the genera of the rejected claims.

Rejection under 35 U.S.C. §112 2<sup>nd</sup> paragraph

Claim 5 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. The Examiner maintains that claims must stand alone to define the invention and incorporation by express reference to the specification and/or drawings is not

permitted. Applicants have obviated this rejection by incorporating the claimed compounds into claim 5.

Prior Art Rejections

Rejection under 35 U.S.C. § 102

Claims 1, 2, 6, 9, and 10 have been rejected under 35 U.S.C. §102(b) as being anticipated by McCaully et al. ( U.S. Patent No. 3,611,925, example 3, abstract, column 3 fourth paragraph, column 4).

The Examiner alleges that the reference teaches the compound shown in Section 3, which is central nervous system depressant, and pharmaceutical composition thereof. Applicants, without acquiescing to the Examiner's rejection, have obviated the rejection by the amendments to claim 1.

III. Conclusion

In view of the above amendments and remarks, notification of a favorable consideration is respectfully requested.

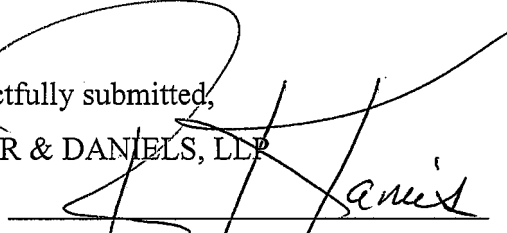
Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below to expedite prosecution.

The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 50-3380, referencing Attorney Docket No. 978725.6/MPG-P0005.

Respectfully submitted,

BAKER & DANIELS, LLP

By



Ronald J. Kamis, Reg. No. 41,104  
Baker & Daniels LLP  
805 15<sup>th</sup> Street, N.W., Suite 700  
Washington, D.C. 20005  
Telephone: (202) 312-7029  
Facsimile: (202) 312-7441